Attorney Docket No: 38-15(52826)B

REMARKS

PRIORITY

Applicants thank the Examiner for withdrawal of the objection to the claim for priority.

REASONS FOR AMENDMENTS

CLAIMS

Applicants request that claims 3 and 16 be cancelled without prejudice and that amendments to claims 1 and 14 be made. As more specifically discussed below, Applicants believe these amendments place the claims in condition for allowance as well as present the claims in better form for consideration and reduce issues of patentability under §112 relating to indefiniteness, written description, and enablement. None of these amendments add new material to the application.

REJECTIONS

CLAIMS ARE DEFINITE UNDER 35 USC §112, SECOND PARAGRAPH

Applicants wish to thank the new Examiner for withdrawal of the rejection of alleged indefiniteness of claim 5.

The Examiner has maintained the rejection of claims 1 – 17 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention, "because of the recitation, "emb5" in claims 1 and 14". The Examiner alleges that it is "unclear which emb gene is referred to by "the" maize emb5 gene".

Applicants believe that the claims as originally filed, and as previously amended, are definite under 35 USC §112, second paragraph for the reasons previously presented. Nonetheless, to expedite allowance of the application, Applicants submit the current proposed amendments, which should serve to obviate the Examiner's concerns. The proposed amendments include amendments of independent claims 1 and 14 to more clearly describe the claimed invention, and cancellation of claims 3 and 16 for redundancy. The promoter of claims 1 and 14 is now described to be an embryo-specific promoter derived from the 5' regulatory region of a

maize *emb5* gene and comprising at least 100 contiguous nucleotides of SEQ ID NO:1. With these proposed amendments, Applicants believe that the Examiner's rejections under 35 USC §112, second paragraph, are made moot, and respectfully request that the rejections be withdrawn.

CLAIMS COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT UNDER 35 USC §112, FIRST PARAGRAPH

The present Examiner has maintained the previous rejection of claims 1, 3 – 14, and 16 – 18, under 35 USC §112, first paragraph, for lack of written description. More specifically, the Examiner alleges that "the nucleotide sequence of SEQ ID NO: 1 does not identify other maize emb5 genes or their promoters. Further, the specification does not correlate embryo-specific promoter activity with any contiguous 100 nucleotide sequence of SEQ ID NO: 1."

Applicants respectfully maintain that claims 1, 3 – 14, and 16 – 18 as originally filed, and as previously amended, comply with the written description requirement of 35 USC §112, first paragraph. In particular, Applicants assert that SEQ ID NO: 1 is fully and literally described as a promoter having the nucleic acid sequence of SEQ ID NO: 1, derived from the 5' regulatory region of a maize *emb5* gene identified in the specification by the public accession number M90554, and exhibiting promoter activity in plants. Applicants further continue to maintain that in doing so, the specification *prima facie* describes each and every promoter comprising at least 100 contiguous nucleotides of SEQ ID NO:1. Applicants submit that it would be immediately clear to one skilled in the art what is claimed as an aspect of the Applicants' invention, that is, each and every nucleotide sequence comprising at least 100 contiguous nucleotides of SEQ ID NO:1 and having embryo-specific promoter activity in plants is claimed.

Applicants once again point out that support for identifying such derivative promoters, which exhibit promoter activity similar or identical to that of the promoter having SEQ ID NO:1, is profuse within the specification as filed, and that such derivative promoters could be assayed for promoter activity by the various techniques disclosed by the specification. See, for instance, Examples 2, 3, 4, and 5 of the specification, which explicitly describe detection of promoter activity and especially embryo-specific promoter activity, by use of a reporter gene (*uidA* or GUS) operably linked to a promoter of the invention.

Applicants wish to direct the present Examiner to review the Board of Patent Appeals and Interferences' Opinion in support of the Decision on Appeal under 35 USC §134 in *Ex parte* McElroy (United States Patent Application No. 09/532,806, now United States Patent Number 6,747,189, issued 8 June 2004), which is part of the public record and contains relevant discussions of compliance with 35 USC §112, first paragraph. A copy of this Opinion was previously provided in Applicants' Response to the Office Action mailed 18 November 2004.

Applicants further direct the Examiner to the Board of Patent Appeals and Interferences' Opinion in support of the Decision on Appeal under 35 USC §134 in *Ex parte* Houmard (United States Patent Application No. 09/757,089, which with the present application is commonly assigned to Monsanto Technology LLC), which Opinion was mailed 29 April 2005 and is part of the public record. A copy of this Opinion, including the Remand and Order, is attached for the Examiner's convenience. Applicants submit that the Board's views in the McElroy and Houmard cases are especially relevant to the outstanding rejections because the natures of the claimed inventions are highly parallel, but for the specific sequence.

Thus, Applicants respectfully traverse the rejection on the same grounds previously presented, but propose the current amendments, which should resolve the Examiner's concerns. The proposed amendments include amendments of independent claims 1 and 14 to more clearly describe the claimed invention, and cancellation of claims 3 and 16 for redundancy. The promoter of claims 1 and 14 is now described to be an embryo-specific promoter derived from the 5' regulatory region of a maize *emb5* gene and comprising at least 100 contiguous nucleotides of SEQ ID NO:1. With these proposed amendments, Applicants believe that the Examiner's rejections under 35 USC §112, first paragraph, are made moot, and respectfully request that the rejections be withdrawn.

CLAIMS COMPLY WITH THE ENABLEMENT REQUIREMENT UNDER 35 USC §112, FIRST PARAGRAPH

The Examiner has maintained the rejection of claims 1, 3 -14, and 16 -18 under 35 USC §112, first paragraph, for failing to enable the full scope of the claimed invention. The Examiner further alleges that "one skilled in the art cannot conclude that any other nucleotide sequence is a homolog without knowing the function of the coding sequence naturally operably linked to SEQ ID NO:1".

Applicants respectfully maintain that claims 1, 3 – 14, and 16 – 18, as originally filed and as previously amended, comply with the enablement requirement of 35 USC §112, first paragraph. Applicants assert that the specification clearly provides an identified sequence for a maize *emb5* gene, and that one skilled in the art would know to use this sequence for the basis of a routine search for homologues, for which the promoters of such identified *emb5* homologues can be cloned using procedures similar to those described in Example 1. One skilled in the art would further know to confirm the expression pattern of such identified homologues. Applicants respectfully point out that no claim is or has been made regarding the function of the maize *emb5* gene identified in the specification by the public accession number M90554, or of any *emb5* homologues, other than that the expression of such a gene is embryo-specific.

Applicants thus maintain that the specification as filed fully enables one skilled in the art to identify structural homologues of the maize *emb5* gene identified in the specification by the public accession number M90554, to clone promoters of such identified homologues, and to determine the promoter activity of such promoters, for example, by using methods for detecting promoter activity in plant embryos, including transgenic plant embryos, e. g., plant embryos transgenic for an identified *emb5* homologue. Applicants do not contest the need for some experimentation, but continue to maintain that the experimentation necessary to test a given sequence (such as a fragment of SEQ ID NO:1, or a promoter of an identified *emb5* homologue) for promoter activity is neither undue nor non-routine.

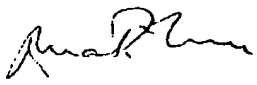
Applicants respectfully maintain their traversal of the rejection on the same grounds previously presented, and again remind the Examiner of the Board of Patent Appeals and Interferences Opinions in *Ex parte* McElroy and *Ex parte* Houmard. Nonetheless, Applicants propose the current amendments in the interest of proceeding to allowance. The amendments as proposed should resolve the Examiner's concerns. Applicants thus believe that the Examiner's rejections under 35 USC §112, first paragraph, are made moot, and respectfully request that the rejections be withdrawn.

Applicants thank the Examiner for consideration of the proposed amendments and respectfully request entry of the amendments. Applicants believe that entry of the amendments proposed herein would resolve the Examiner's concerns, and respectfully request that the rejections be withdrawn. Applicants respectfully submit that the claims are ready for examination and in condition for allowance.

Attorney Docket No: 38-15(52826)B

If the Examiner has any questions regarding this application, the Examiner is encouraged to contact Applicants' undersigned agent at (860) 572-5217 (telephone) or (860) 572-5280 (fax).

Respectfully submitted,



Maria Margarita D. Unson
Registration Number 53,711
Agent for Applicants

Date: 27 October 2005

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NANCY HOUMARD, LUCILLE B. LACCETTI, ALBERT B. KAUSCH and EMIL M. OROZCO, JR.
(hereafter Houmard)

Appeal No. 2005-0409
Application No. 09/757,089[1]

Before GRON, GRIMES and GREEN, Administrative Patent Judges.

GRON, Administrative Patent Judge.

DISCUSSION, REMAND and ORDER

We have before us an appeal under 35 U.S.C. § 134 of an examiner's final rejections of Claims 1, 5-12, 17-19, 22-29, 31-35, 38, 42-51, 82, 85-92, 94-98, 101, 105-123, 126 and 127 of Application 09/757,089 under 35 U.S.C. § 112, first paragraph, for noncompliance with both its written description and enablement requirements (Examiner's Answer, p. 2 (EA2)). Claims 1 and 5-13 presently pending in Application 09/757,089 are reproduced below:

[1] Application for patent filed January 9, 2001.

Appeal No. 2005-0409
Application No. 09/757,089

1. An isolated nucleic acid comprising a maize chloroplastic F16BP aldolase promoter, said promoter comprising from 95 to 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

5. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 110 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

6. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 125 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

7. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 250 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

8. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 400 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

9. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 750 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

10. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 1000 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

11. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 1500 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

12. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises from about 1750 to about 1864 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:2.

13. The isolated nucleic acid of claim 1, wherein said chloroplastic F16BP aldolase promoter comprises the nucleic acid sequence of SEQ ID NO:2.

Appellants' Brief On Appeal was received in Tech Center 1600/2900 on July 9, 2003. The Examiner's Answer was mailed January 8, 2004.

On March 10, 2004, Appellants filed a Reply Brief accompanied by a copy of the August 29, 2003, decision of the Board of Patent Appeals and Interferences in Appeal No. 2003-0936 under 35 U.S.C. § 134 reversing an Examiner's Final Rejection of Claims 1, 4-54, and 85-131 of Application 09/532,806, filed March 21, 2000, under 35 U.S.C. § 112, first paragraph, also for noncompliance with its written description and enablement requirements. Application 09/532,806 of Appeal No. 2003-0936 and Application 09/757,089 of this appeal are commonly assigned to Monsanto Technology LLC. LUCILLE B. LACCETTI and EMIL M. OROZCO are named coinventors of the subject matter claimed in both applications, and each application was examined in Tech Center 1600. Claims 1 and 4-14 of Application 09/532,806 of prior Appeal No. 2003-0936 are reproduced below:

Appeal No. 2005-0409
Application No. 09/757,089

1. An isolated nucleic acid comprising a maize GRP promoter comprising at least 95 contiguous bases of SEQ ID NO:1.

4. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 110 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

5. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 125 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

6. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 250 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

7. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 400 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

8. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 750 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

9. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 1000 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

10. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 1500 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

11. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 2000 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

12. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 2500 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

13. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises from about 3000 to about 3536 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:1.

14. The isolated nucleic acid of claim 1, wherein said GRP promoter comprises the nucleic acid sequence of SEQ ID NO:1.

Appellants informed the examiner in Part VII of the Reply Brief, Summary of the Reply (RB3-4):

> The same written description and enablement issues on appeal were recently decided by the Board in U.S. Patent Appl. Ser. No. 09/532,806. The specification and claims in that case were substantively the same as in this case. Both applications claimed a maize promoter sequence including fragments of at least 95 bp of the full length sequence and were rejected by the Examiner for an alleged lack of written description and enablement. The positions taken by the Examiner were essentially the same as in this case and were handled by the same Supervisory and Primary Examiners. The Board reversed the Examiner on both rejections in the '806 application, noting that the claims had literal support in the specification and that the substantial guidance provided by the specification rendered any experimentation needed to practice the full scope of the claimed invention routine. Given that the same substantive facts and legal issues are presented on appeal here, Appellants respectfully request that the same analysis be applied by the Board and the Examiner be reversed.
>
> The Answer fails to address the shortcomings of the written description rejection noted in Appellants' Brief.
> . . . .

The examiner responded to Appellants' Reply Brief by entering it, noting that the Reply Brief with the prior decision of the Board attached had been considered, and forwarding the application upon which the present appeal is based to the Board:

Appeal No. 2005-0409
Application No. 09/757,089

> The Reply Brief filed 3/10/2004 has been entered and considered. The application has been forwarded to the Board . . . for decision on the appeal.
>
> Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum . . . .

We understand that inquiries whether specifications satisfy the requirements of the first paragraph of 35 U.S.C. § 112 for the full scope of the claimed subject matter are claim and fact specific. Each case must stand on its own facts. Vas-Cath Inc. V. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Nevertheless, prior decisions of the Board provide invaluable instruction and guidance, especially where, as here, there are marked similarities between the presentations of the subject matter claimed, the disclosures in the supporting specifications, and the acknowledged skill and state of the art. Moreover, the cases allegedly have common assignees, common inventors and common examiners.

It is a hallmark of our legal system that similar cases are treated similarly. We do not, and no participant in this time-honored system may, casually disregard the outcome of cases with similar facts in prior decisions. Accordingly, we enter the following order.

Appeal No. 2005-0409
Application No. 09/757,089

Order

It is ORDERED that Application 09/757,089 is remanded to the primary examiner in charge of prosecution for reconsideration of the prior decision of the Board in Appeal No. 2003-0936, entered August 29, 2003, and comparison of the claimed subject matter, supporting disclosures, and acknowledged skill and state of the prior art in the applications relating to Appeal 2003-0936 and this appeal; and

It is FURTHER ORDERED that after reconsidering the prior decision of the Board in Appeal No. 2003-0936, entered August 29, 2003, and comparing the claimed subject matter, supporting disclosures, and acknowledged skill and state of the prior art in the applications relating to Appeal 2003-0936 and this appeal, should the examiner maintain the rejections presently appealed, the examiner shall not only reply to each and every point raised in appellants' Reply Brief citing and/or relying on the Board's prior decision in Appeal No. 2003-0936, but the examiner also shall distinguish the facts and law of the two appeals which support a decision in this appeal contrary to our decision in Appeal No. 2003-0936.

Appeal No. 2005-0409
Application No. 09/757,089

This application, by virtue of its "special" status, requires an immediate action. Manual of Patent Examining Procedure § 708.01 (8th ed., rev. 2, May 2004). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMAND

TEDDY S. GRON
Administrative Patent Judge

ERIC BURTON GRIMES
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

TSG/jlb

Appeal No. 2005-0409
Application No. 09/757,089

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